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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/496,893	02/02/2000	Stephen J. Brown	7553.00030 / 00-0220	6810

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EXAMINER	
SMITH, CAROLYN L	
ART UNIT	PAPER NUMBER
1631	

MAIL DATE	DELIVERY MODE
12/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 09/496,893	**Applicant(s)** BROWN, STEPHEN J.	
	Examiner Carolyn L. Smith	**Art Unit** 1631	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 28 November 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____months from the mailing date of the final rejection.
   b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: 83-98.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

Carolyn L Smith
Primary Examiner
Art Unit: 1631 12/17/07

Continuation of 11. does NOT place the application in condition for allowance because: the rejections are maintained, as discussed below.

35 USC 112, 1st paragraph, NEW MATTER

Applicant argues that support for the phrase "selecting one or more disease-influencing genes needed to be processed for medical research" can be found on page 11, lines 8-19, of the specification. It is noted that the passage recites "to find disease-influencing genes" which is different from "selecting one or more disease-influencing genes". To find and to select are not commensurate in scope as "find" may indicate that the information was not previously known, while "select" can be interpreted, for example, to be a user action of deciding which genes from an already verified list to choose. It is noted that "to be processed for medical research" and "to use the disease-influencing genes or substances to find drug candidates or drug targets" are not commensurate in scope as the first mention phrase is broader. Processed for medical research encompasses activities such as clinical trials, developing pharmaceuticals and kits, diagnosing disease, etc. which is broader than just finding drug candidates or targets.

Applicant argues that "using environmental information about an individual in conjunction with the individual's genotype to find disease-influencing genes" in the specification provides adequate written support for "to identify one or more individuals having a disease-influencing gene". This statement is found unpersuasive as the first phrase is finding genes which is vastly different from identifying individuals.

Applicant argues that the phrase "that represents a subset of said genotype information associated with each of said groups" is supported by differences in Figures 15-18 and 20 found when comparing the genotype information of individuals between groups would reasonably be described as a subset of the total genotype information associated with the groups. This statement is found unpersuasive as grouping individuals, categorizing each group, and finding a disease-influencing substance (i.e. Figure 19) does not mention or infer any subset of genotype information associated with each group. Applicant argues another example provided in the specification as originally filed is the use of data mining techniques to find differences in gene sequences (see page 31, lines 1-10 of the specification) and argues it is inherent that a report of the results of the data mining (e.g., individual gene sequences A and B in the example) would be generated or else the data mining would not be useful or advantageous. This statement is found unpersuasive as the passage provides support for finding and identifying a gene, not representing a subset, which is differs in scope. Applicant argues, in connection with FIGS. 2 and 10, the specification states that specific techniques for writing a report generator program to display data are well known in the software art (e.g., see page 24, lines 12-21 of the specification as originally filed). This statement is found unpersuasive as displaying data does not represent a subset.

35 USC 112, 1st paragraph, LACK OF ENABLEMENT

Applicant argues FIGS. 1, 2 and 13-20 along with the respective descriptive text describes the subject matter of the presently pending claims in such a way as to enable one skilled in the art to which it pertains or with which it is most connected, to make and/or use the claimed invention. In particular, the specification provides numerous examples of genotype information and sources (e.g., companies) from which genotype information can be received or obtained (see page 4, line 14 through page 9, line 25 of the specification). The specification further provides examples of comparing genotype information based on groups of individuals formed based upon responses to scripted queries (see FIGS. 16, 18 and 20 as originally filed). These statements are found unpersuasive as polymorphisms that exist in human genes that result in an unpredictable length and difficulty in a research project that simply clusters individuals via queries regarding behavior or other characteristics to then isolate or focus on one or more disease-influencing genes.

The Office Action states that Doberstein et. al. (U.S. Pub. No. 2003/0068649; hereinafter Doberstein) was cited regarding paragraphs 0003-0008 to support the position that numerous difficulties are involved in relating gene sequences to other factors even utilizing modern bioinformatics tools. Applicant summarizes portions of Doberstein, including "[t]he fundamental difficulties associated with working with large collections of nucleic acid sequences, such as genetic libraries, are alleviated by linking the expressed peptide with the genetic material which encodes it." (paragraph [0006], lines 1-4 of Doberstein). Doberstein then describes commonly used methods of linking proteins to coding nucleic acid molecules (see paragraphs [0006]-[0007] of Doberstein). Doberstein further states that the invention disclosed by Doberstein provides a genetic library which allows easy association of a variant or unknown peptide and its coding sequence and a method of use (see paragraph [0008] of Doberstein). Applicant argues that the statement in the Office Action that "[t]hus, the clustering of individuals, which has been known for many diseases already has not predictably resulted in gene identification" (see page 5, lines 18-21 of the Office Action) is directly contradicted by the example of Myriad Genetics, Inc. on page 7, lines 12-21 of the specification as originally filed. This statement is found unpersuasive as the art is considered unpredictable as noted by Doberstein et al. (0004).

Applicant argues that Examiner made a determination of enablement based on personal opinion. This statement is found incorrect as the determination has been based on the Wands factors and fully supported by objective evidence from Doberstein as to the unpredictability in this art. Applicant argues that the experimentation is routine business which is found unpersuasive due to the unpredictable nature of the art which leads to undue experimentation.

35 USC 112, 2nd paragraph

Applicant argues that the mere fact that the body of the claim recites additional elements that do not appear in the claim's preamble does not render the claim indefinite. While this is agreed, it is noted that a claim is indefinite when the preamble recites information that differs or is missing from the body of the claim, as in the current 35 USC 112, 2nd paragraph rejections. Applicant summarizes instant claims 83 and 90 and cites pages 7 and 11 of the specification. Applicant argues that comparing genotype information and generating a report

would be reasonable steps in a method for selecting one or more disease-influencing genes. While they may be part of the method, it is unclear if the preamble is intended to limit the method and what relationship is intended between the preamble and the method steps. It is also noted that while the claims can be read in light of the specification, portions of the specification may not be read into the claims.

Applicant's arguments are deemed unpersuasive for the reasons given above.

CAROLYN L. SMITH
PRIMARY EXAMINER
12/17/07